

In December 2000, Congress enacted Public Law 106-554, which among other provisions, directed FDA to "reexamine existing condom labels" and "determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases* * *." FDA is recommending labeling changes intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and

repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA believes that this is a one-time burden, because once a label is redesigned, it can be used indefinitely.

In the *Federal Register* of November 14, 2005 (70 FR 69156), FDA published a 60-day notice soliciting public comment on the information collection provisions, contained in the draft special controls guidance document then entitled "Labeling for Male Condoms Made of Natural Rubber Latex." FDA has subsequently retitled the special controls guidance document containing these information collection

provisions to avoid confusion between the guidance established as a special control for condoms classified under 21 CFR 884.5300 by the final rule published elsewhere in this issue of the *Federal Register* and the November 2005 draft guidance, which remains available (but not for implementation) in conjunction with the pending proposal to amend another classification. No comments were received on the information collection provisions in response to the 60-day notice.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
35 ²	34	1,190	12	14,280
3 ³	34	102	12	1,224
Total				15,504

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Current manufacturers for year one.

³ New Manufacturers for years two and three.

The reporting burden hours to respondents in the first year is a one-time burden of 14,280 hours. FDA expects three new manufacturers or repackagers to enter the market yearly, and collectively have a one-time burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA's database of premarket submissions. The remaining figures were derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to redesign the labeling for OTC drugs is an appropriate proxy for the estimated burden to redesign condom labeling. Cost estimates were adjusted to account for inflation using the producer price index.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807 subpart E have been approved under OMB control no. 0910-0120; the collections of information under 21 CFR part 820 have been approved under OMB control no. 0910-0073; and the collections of information in part 801 (21 CFR part 801) have been

approved under OMB control no. 0910-0485.

The collection of information under § 801.437 does not constitute a "collection of information" under the PRA. Rather, it is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-E-0093]

Determination of Regulatory Review Period for Purposes of Patent Extension; IXEMPRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IXEMPRA and is publishing this notice of that determination as required by law. FDA has made the determination

because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and

an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product IXEMPRA (ixabepilone). IXEMPRA in combination with capecitabine is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane. IXEMPRA as monotherapy is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IXEMPRA (U.S. Patent No. 6,605,599) from Bristol Myers Squibb Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 22, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of IXEMPRA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for IXEMPRA is 3,002 days. Of this time, 2,818 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* July 30, 1999. The applicant claims June 30, 1999, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was July 30, 1999, which was thirty days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* April 16, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for Ixemptra (NDA 22-065) was initially submitted on April 16, 2007.

3. *The date the application was approved:* October 16, 2007. FDA has verified the applicant's claim that NDA 22-065 was approved on October 16, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 854 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by January 9, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 11, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: October 20, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-E-0229]

Determination of Regulatory Review Period for Purposes of Patent Extension; TYKERB

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TYKERB and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug